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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,523	05/30/2000	Xiao-Mai Zhou	A7483	8284
23373	7590	02/10/2005	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			DAVIS, MINH TAM B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/580,523	<b>Applicant(s)</b> ZHOU, XIAO-MAI	
	<b>Examiner</b> MINH-TAM DAVIS	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,10,16,19,22,25,31-62 and 70 is/are pending in the application.
- 4a) Of the above claim(s) 31-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,10,16,19,22,25 and 70 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/30/03</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claim 13 and adds new claim 70, which is related to claims 1, 3, 10, 16, 19, 22 and 25 and are not new matter.

The Examiner apologizes that claim 62, which was not examined, was inadvertently not included in the pending claims.

Claims 1, 3, 10, 16, 19, 22, 25, 31-62, and 70 are pending, and Claims 31-62 have been withdrawn from further consideration by the Examiner under 37 CFR 1.142(b) as being drawn to non-elected invention.

Accordingly, claims 1, 3, 10, 16, 19, 22, 25 and 70 are being examined.

The following are the remaining rejections.

### **INFORMATION DISCLOSURE STATEMENT**

The references in the information disclosure statement of 05/30/03 have been reviewed, and a signed PTO1449 is enclosed therewith.

### **OBJECTION**

1. Claims 1, 3, 10, 16, 19, 22, 25 and 70 are objected to, for the use of the language "BH3 domain", as the sole means of identifying the claimed fragment, because different laboratories may use the same laboratory designations to define completely distinct

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peptide fragments. Amendment of the claims to include physical and/or functional characteristics of "BH3 domain" which unambiguously define "BH3 domain" is required.

2. Claim 3 appears to be free of prior art but is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent forms.

### **REJECTION UNDER 35 USC 102(e), NEW REJECTION**

Claims 1, 10, 16, 19, 22, 25 and 70 are rejected under 35 USC 102(e) as being anticipated by US 5,965,703, of record.

Claims 1, 10, 13, 16, 19, 22, 25 are drawn to:

- 1) A mutant Bcl-X<sub>L</sub> /Bcl-2 associated cell death regulator polypeptide (BAD) which has an amino acid sequence "**at least 95% homologous to SEQ ID NO:1**", which has an amino acid substitution at the position "**corresponding**" to position 118 of SEQ ID NO:1, wherein said amino acid is alanine, or not alanine, or an amino acid conservative for alanine, or an amino acid conservative for alanine which is an amino acid other than glycine, wherein said mutant BAD has cell death promoting activity in vitro and 2) A fragment of said mutant BAD, wherein **said fragment comprises the BH3 domain and has "cell death promoting activity" in vitro** (claims 1, 16, 19, 22),
- 2) Said mutant BAD or fragment thereof binds Bcl-X<sub>L</sub> or /Bcl-2 (claim 10),
- 3) The mutant BAD or fragment thereof of claim 16, wherein said alanine enhances the in vitro cell death promoting activity of said mutant BAD or fragment thereof (claim 70),

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4) A mutant BAD or fragment thereof **“comprising” an amino acid sequence “corresponding” to position 103-123 of SEQ ID NO:1**, with the proviso that the amino acid at the position **“corresponding”** to position 118 or SEQ ID NO:1 is alanine, or an amino acid conservative of alanine, wherein said mutant BAD or fragment thereof has cell death promoting activity in vitro (claim 25).

US 5,965,703 teaches a human Bcl-X<sub>L</sub> /Bcl-2 associated death promoting BAD sequence, SEQ ID NO:2 (claim 1, and column 3, lines 25-32), which is 100% identical to the full length of the claimed SEQ ID NO:1, from amino acids 1 to 168, as shown by MPSRCH sequence similarity search (MPSRCH search report, 2001, 09-580523-1b.ra1, pages 1-2, of record).

US 5,965,703 also teaches a fragment of no greater than 95 contiguous amino acids of the 3'end of SEQ ID NO:2, wherein the fragment binds Bcl-X<sub>L</sub> or /Bcl-2 (claim 3).

It is noted that in view of a lack of a definition of “corresponding”, any amino acid including alanine or conservative amino acid for alanine at any position of SEQ ID NO:2 taught by US 5,965,703 could “correspond” to position 118 of SEQ ID NO:1, and any amino acid sequence of SEQ ID NO:2 taught by US 5,965,703 could “correspond” to positions 103-123 of SEQ ID NO:1.

It is further noted that the instant specification discloses the BH3 domain is encoded by amino acid positions 114-122 of SEQ ID NO:1 (p.14), wherein SEQ ID NO:1 has 168 amino acid in length. Thus the BH3 domain is within the 95 contiguous amino acids of the 3'end of SEQ ID NO:1.

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The claimed polypeptide, and fragment thereof seems to be the same as the prior art polypeptide, and fragment thereof.

Although the reference does not specifically teach that the BAD polypeptide is a mutant or has an amino acid substitution, or that the substituted alanine enhances the in vitro cell death promoting activity, and does not teach a fragment thereof, comprising the BH3 domain, however, the claimed mutant BAD and fragment thereof appear to be the same as the prior art polypeptide and fragment thereof. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

February 05, 2005

SUSAN UNGAR, PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Susan Ungar', is written below the printed name and title.